This Page Is Inserted by IFW Operations and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

P. 03/13

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-4 (Canceled).

- 5. (Previously presented): A device for sampling body fluid, comprising:
 - a) a main body defining a capillary channel;
 - b) a lancet disposed within said capillary channel and defining an annular space between said lancet and said main body;
 - c) wherein said lancet is selectively advancable and retractable; wherein said capillary channel is dimensioned to draw a body fluid into said annular space through capillary action;

at least one testing element in communication with said annular space; wherein said testing element is a test strip; and wherein said test strip is radially mounted around said lancet.

Claims 6-21 (Canceled).

- 22. (Previously presented): A system for sampling and testing a body fluid, comprising:
 - a) a main body defining a capillary channel;
 - b) a lancet disposed within said capillary channel and defining an annular space between said lancet and said main body;
 - c) wherein said lancet is selectively advancable and retractable;
 - d) wherein said capillary channel is dimensioned to draw a body fluid into said annular space through capillary action;—and,

Response to Office Action Serial No. 10/054,270 Group Art Unit 3731 Attorney Docket No. 7404-318 Page 2 of 11

e) a testing means for testing the body fluid drawn into said annular space; and

a holder holding said testing means in said annular space.

- 23. (Original): The system of claim 22 wherein said testing means comprises at least one test element in communication with said annular space.
- 24. (Withdrawn): The system of claim 22 wherein said testing means comprises analysis equipment operable to test the body fluid in said annular space.
- 25. (Withdrawn): The system of claim 24 wherein said testing means further comprises electrochemical sensors mounted within said annular space and in communication with said analysis equipment.
- 26. (Withdrawn): The system of claim 24 wherein said main body is placed in said analysis equipment after a body fluid sample is collected.
- 27. (Withdrawn): The system of claim 26 wherein said testing device tests the body fluid using optical transmittance, reflectance or flourescence.
- 28. (Withdrawn): The system of claim 26 wherein said testing device tests the body fluid using electrochemical sensors situated to communicate with said annular spacc.

Claims 29-31 (Canceled).

Response to Office Action Serial No. 10/054,270 Group Art Unit 3731 Autorney Docket No. 7404-318 Page 3 of 11

JUL-06-04 TUE 15:17

- (Previously presented): A method of obtaining a fluid sample from the body of 32. a person, comprising the steps of:
 - a) placing an apparatus having a defined capillary channel and a lancet disposed in said capillary channel that together define a capillary space adjacent tissue at a desired sample location;
 - b) advancing the lancet disposed within said capillary channel so that said lancet incises tissue at an incision point in the desired sample location;
 - c) retracting said lancet into said capillary channel; and,
 - d) acquiring body fluid expressed from the body at the incision point into said capillary space through capillary action.
- 33. (Original): The method of claim 32 further comprising the step of testing the acquired body fluid while the fluid is contained in said capillary channel.
- 34. (Withdrawn): The method of claim 32 further comprising the step of transferring the fluid from said capillary channel to a testing element and thereafter testing the fluid.
- 35. (Original): The method of claim 32 further comprising the step of testing the acquired body fluid with testing means communicating with said capillary channel.
- 36. (Original): The method of claim 33 further comprising the step of testing the acquired body fluid for a blood glucose level.

Claims 37-43 (Canceled).

Response to Office Action Serial No. 10/054,270 Group Art Unit 3731 Attorney Docket No. 7404-318 Page 4 of 11

44. (Previously presented): A body fluid sampling device, comprising: a body;

a lancet slidably received in the body to lance an incision in skin, wherein the lancet and the body define a capillary space that is sized to draw the body fluid via capillary action; and

a test means disposed in the capillary space to test the body fluid drawn by the capillary space.

Claim 45 (Canceled).

- 46. (Currently amended): The system of claim 22 45, wherein said holder includes an opening defined in said main body.
- . 47. (Previously presented): The system of claim 22, further comprising a retraction mechanism configured to retract said lancet.
- 48. (Previously presented): The system of claim 47, wherein said retraction mechanism includes a spring disposed in said annular space.
- 49. (Previously presented): The system of claim 22, wherein said annular space is between 10 and 500 μm .
- 50. (Previously presented): The system of claim 22, wherein said annular space is between 20 and 200 µm to optimize fill time.
- 51. (Previously presented): The system of claim 22, wherein said lancet is hydrophilic.

Response to Office Action Serial No. 10/054,270 Group Art Unit 3731 Attorney Docket No. 7404-318 Page 5 of 11

- 52. (Previously presented): The system of claim 51, wherein said lancet is coated with a hydrophilic material.
 - 53. (Previously presented): The system of claim 22, wherein: said main body has an interior surface defining said capillary channel; and said interior surface is hydrophilic.
- 54. (Previously presented): The method of claim 33, wherein said testing the acquired body fluid includes optically testing the acquired body fluid.
- 55. (Previously presented): The device of claim 44, wherein the test means includes a test strip.
- 56. (Previously presented): The device of claim 44, further comprising a holder holding the test means in the capillary space.
- 57. (Previously presented): The device of claim 56, wherein the holder includes an opening defined in the body.
- 58. (Previously presented): The device of claim 44, further comprising a retraction mechanism configured to retract the lancet.
- 59. (Previously presented): The device of claim 58, wherein the retraction mechanism includes a spring surrounding the lancet.
- 60. (Previously presented): The device of claim 44, wherein the capillary space is sized between 10 and 500 µm.

Response to Office Action Serial No. 10/054,270 Group Art Unit 3731 Attorney Docket No. 7404-318 Page 6 of 11 JUL-06-04 TUE 15:17

- 61. (Previously presented): The device of claim 44, wherein the capillary space is sized between 20 and 200 µm.
- 62. (Previously presented): The device of claim 44, wherein the lancet is hydrophilic.
- 63. (Previously presented): The device of claim 62, wherein the lancet is coated with a hydrophilic material.
- 64. (Previously presented): The device of claim 44, wherein the body is hydrophilic.
- 65. (Previously presented): The device of claim 64, wherein the body is coated with a hydrophilic material around the capillary space.
- 66. (Previously presented): The device of claim 44, wherein the body has a generally cylindrical shape.
- 67. (Previously presented): The device of claim 44, wherein the lancet has a generally cylindrical shape.
- 68. (Previously presented): The device of claim 44, wherein the body is made of a bio-compatible plastic.
- (Previously presented): The device of claim 44, wherein the test means б9. is optically reactive.
- 70. (Previously presented): The device of claim 44, wherein at least a portion of the body adjacent the test means is transparent. Response to Office Action Serial No. 10/054-270

Group Art Unit 3731 Attorney Docket No. 7404-318 Page 7 of 11

- 71. (Previously presented): The device of claim 44, wherein the body is transparent.
- 72. (Previously presented): The device of claim 44, wherein the lancet is adapted to advance from the body a distance between approximately 0.05 mm and 3 mm.
- 73. (Withdrawn): The device of claim 44, further comprising a sealing member enclosing an end of the capillary space.
- 74. (Withdrawn): The device of claim 73, wherein the sealing member includes a safety cap covering the lancet.
- 75. (Withdrawn): The device of claim 44, the test means includes a membrane.
- 76. (Withdrawn): The device of claim 44, wherein the test means includes two or more testing elements.
- 77. (Withdrawn): The device of claim 44, wherein the test means includes one or more electrochemical sensors disposed within the capillary space.

Response to Office Action Serial No. 10/054,270 Group Art Unit 3731 Attorney Docket No. 7404-318 Page 8 of 11

P. 10/13

- 78. (New): A system for sampling and testing a body fluid, comprising: a main body defining a capillary channel;
- a lancet disposed within said capillary channel and defining an annular space between said lancet and said main body;

wherein said lancet is selectively advancable and retractable;

wherein said capillary channel is dimensioned to draw a body fluid into said annular space through capillary action;

a testing means for testing the body fluid drawn into said annular space; and a retraction mechanism configured to retract said lancet, wherein said retraction mechanism includes a spring disposed in said annular space.

Response to Office Action Serial No. 10/054,270 Group Art Unit 3731 Attorney Docket No. 7404-318 Page 9 of 11